

**Remarks**

Claims 19 and 145-156 are pending.

Claims 145-156 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,393,763 (Black).

Claims 19 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Black as applied to claims 145-156.

**U.S.C. § 102(b) Rejection**

Claims 145-156 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,393,763 (Black).

In the Office Action of July 25, 2007, the Examiner stated

[i]n the examples provided in [Black], raloxifene is administered to “post-menopausal women” (col. 19, lines 15-16 and claim 3), thus anticipating the instantly claimed patient population. Claim 2 of the ‘763 patent recites patients suffering from osteoporosis as instantly claimed in claims 153-156.

The Examiner also stated that Black inherently anticipates claims 145-156 because

In the instant case, it flows from the teachings of Black *et al.* that patients being treated with raloxifene so as to inhibit bone loss will naturally have a reduced likelihood of developing breast cancer. It is clear that Black *et al.* contemplate treating post-menopausal women with raloxifene and further contemplate treating patients having osteoporosis with raloxifene (*i.e.*, the same patient populations as instantly claimed). Because the same patient populations are being treated with the same drug, the instantly claimed result of such treatment would naturally occur in the patients being treated in the ‘763 patent.

Black *et al.* discloses methods for inhibiting the loss of bone that results from a lack of endogenous estrogen and the resulting osteoporosis, for example, post-menopausal osteoporosis.

In the sole independent claim pending, Claim 145 is directed to a “method for reducing the likelihood of incurring or developing estrogen-dependent breast cancer in a post-menopausal woman diagnosed as being in need of such therapy.” (emphasis added). There is no discussion in Black about diagnosing or screening patients, who are to be administered raloxifene for osteoporosis, for breast cancer risk reduction or prevention. Applicants respectfully submit there is no teaching and no expectation that women who are so diagnosed represent all post-menopausal women. Applicants respectfully assert the present claims, therefore, do not flow from the teachings of Black. Therefore, Black does not anticipate the present claims.

The Examiner further stated that the term “about” in Claim 145 “expands the range of

raloxifene that can be administered to a patient to reasonably include any effective amount, including those doses recited in Black *et al.*” However, the present application defines “about 60 mg” to “encompass 55 to 65 mg of raloxifene hydrochloride, while encompassing 51.73 to 60.35 mg of the free base.” (Page 15, lines 30-32.)

**U.S.C. § 103(a) Rejection**

Claims 19 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Black “as applied to claims 145-156.” In the Office Action of July 25, 2007, the Examiner stated that

Claim 19 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Black *et al.* (U.S. Patent No. 5,393,763; Issued Feb. 28, 1995) as applied to claims 145-156, *supra*.

Black *et al.* disclose as applied *supra*. The reference does not explicitly disclose the instantly claimed administration for at least six months. However, in the absence of a showing of unexpected results, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to administer raloxifene for as long was necessary to inhibit bone loss as disclosed in Black *et al.* As such, because the same patient population is being administered the same active agent, it flows from the disclosure of Black *et al.* that such extended treatment will lead to a reduced likelihood of incurring or developing estrogen-dependent breast cancer in post-menopausal women.

(Emphasis added). It appears the Examiner has rejected claim 19 for being inherently obvious. In response to the 103(a) rejection, Applicants, therefore, incorporate by reference the discussion above for the 35 U.S.C. § 102(b) rejection and again state that there is no discussion in Black about diagnosing or screening patients, who are to be administered raloxifene for osteoporosis, for breast cancer risk reduction or prevention. Applicants respectfully submit there is no teaching and no expectation that women who are so diagnosed represent all post-menopausal women. Applicants respectfully submit, therefore, that Claim 19 does not flow from the teachings of Black. Therefore, claim 19 is not obvious over Black.

**Conclusion**

Applicants submit claims 19 and 145-156 are ready for grant.

Respectfully submitted,

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